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TITLE: Evaluating a Novel Sleep-Focused Mind-Body Rehabilitative Program for Veterans with mTBI and Other "Polytrauma" Symptoms: An RCT Study

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4. Introduction

Abstract: The purpose of the study is to evaluate and compare the clinical benefit of two sleep-focused therapeutic interventions: Mind-Body Bridging (MBB) and Supportive Education (SED) on sleep and comorbid mild Traumatic Brain Injury (mTBI) symptoms. We will recruit 142 OEF/OIF veterans with mTBI, who first will undergo a comprehensive evaluation performed by our medical and psychological staff, and then will be assigned to one of the two programs (MBB or SED). Each veteran will receive a total of 6 hours of treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each patient will be evaluated again after treatment has ended. Three months after treatment ends, patients will have another evaluation. Six months after treatment ends, patients will complete follow-up questionnaires. These assessments will help us to evaluate both the efficacy of the therapy programs and any differences in individual treatment response. Additionally, the project will explore underlying mechanisms of action involved in treatment benefits resulting from MBB and SED by using both a biomarker of stress and a physiological measure of sleep (i.e., heart rate variability) as proxy indicators of intermediate mechanisms engaged by MBB and SED.

5. Body

We have continued our recruiting effort. We screened the patient lists obtained from Polytrauma Clinic at VA, sent recruitment letters and made phone calls to follow-up with the letters we sent. We repeatedly posted flyers and brochures at Salt Lake VA and other approved locations and distributed study information to OEF/OIF resource groups. We hired a LCSW to run Bridging groups. The amendment to request data from DoD was approved by local IRB. We are requesting data of OEF/OIF veterans who documented positive screen in TBI clinical reminder from DoD. We discussed the possibility of modifying inclusion and exclusion criteria with the DoD officials in April 2015, which was provisionally approved, pending necessary approval from local IRB and HRPO. We are currently preparing IRB amendment to include mTBI assessment in the screening evaluation. First and Second intervention group participants completed the study. Third group intervention participants completed the 3 month follow-up evaluations. Most fourth group intervention participants completed the post-intervention evaluation. We are planning to start the fifth group intervention in November.

6. Key Research Accomplishments

- continue recruiting of eligible study participants, hired LCSW for the study
- set up online survey (REDCap)
- amendment to request data from DoD approved
- preparing amendment to do mTBI assessment at the screening evaluation
- first and second intervention group participants completed the study.
- 35 Veterans consented to participated in the study
- 21 Veterans completed intervention sessions
- 20 Veterans completed post-intervention evaluation
- 13 Veterans completed 3 month follow-up evaluation
- 7 Veterans completed 6 month follow-up evaluation

7. Reportable Outcomes

Study enrollment is currently ongoing. We do not have any result yet to report here.

8. Conclusions

Study enrollment is ongoing, so we are currently not in a position to reach any conclusion regarding study aims and hypothesized benefits of the experimental intervention program (MBB) as of now. Following the provisional approval from the DoD grant officers concerning potential modifications of study procedures, we are in process of modifying inclusion and exclusion criteria for study participants so that the study will be able to contact veterans who indicated positive screen in TBI clinical reminder at the time of discharge from the military, provided that these veterans are not currently receiving care through VASLCHCS. We plan to submit IRB amendment application to our local IRB in early October 2015.

9. References

None

10. Appendices

None

11. Supporting Data

None